

REMARKS

Summary of 10/15/09 Interview

Applicants would like to thank Examiner Ghali for the courtesy extended during an interview with the undersigned conducted on October 15, 2009 in the Examiner's office. During the interview, the outstanding rejections of claims 1-9, 16-18, 28-31, 35-37, 39-47, 52-54, and 92-93 under § 102 and/or § 103 over Miranda, alone or in combination with Garbe, were discussed. During the interview, the undersigned explained that Miranda disclosed a drug delivery composition that required the presence of a polysiloxane in addition to drug and an acrylate polymer. Accordingly, the undersigned proposed amending the claims to describe the drug delivery composition as "consisting essentially of" an acrylate/methacrylate copolymer and fentanyl, rather than "comprising" the copolymer and fentanyl. The amended claims would exclude Miranda's polysiloxane polymer. The Examiner agreed to consider the amendment, and further proposed amending the claims to recite a copolymer "of" components (i) and (ii), rather than a copolymer "comprising" components (i) and (ii). The undersigned agreed to consider the Examiner's proposal.

Response to Office Action

Claims 30, 31, and 37 have been canceled.

Claims 1, 35, 36, 54, and 92 have been amended, as discussed during the interview, by replacing "comprising" with "consisting essentially of" to characterize the drug delivery composition. In addition, in view of these amendments, claims 1, 35, and 36 have been amended further to recite the optional inclusion of delivery enhancing adjuvants, plasticizers, tackifiers, and combinations thereof. Support for these amendments can be found, e.g., in paragraphs [0036] and [0037] of the published U.S. application (US 2002/0119187 A1).

Claims 39 and 45 have been amended to make them consistent with the "consisting essentially of" language in amended claim 1 on which they directly or indirectly depend. Claims 43-45 have been amended to correct antecedent basis issues by replacing "skin permeation enhancer" with "delivery enhancing agent."

Claim 92 has been amended to place it in the form of a claim to a transdermal drug delivery composition, rather than a device, to make it consistent with the other pending independent claims. Claims 93, which depends on claim 92, has been amended to make it consistent with the “consisting essentially of” language of amended claim 92.

New claims 94-103 have been added. Claim 94 depends on claim 92 and recites a delivery device for the transdermal delivery of fentanyl. It is similar to pending claim 52.

Independent claim 95 is similar to claim 1 except it recites a copolymer “of” certain A and B monomers, and does not recite the optional presence of the delivery enhancing adjuvant, plasticizer, or tackifier. Claims 96 and 97 depend on claim 95, and are similar to claims 93 and 94, respectively.

Independent claim 98 is also similar to claim 1 except it recites numerical ranges for the A and B monomers, and further recites the inclusion of 0-20% by weight of one or more macromonomers copolymerizable with the A and B monomers. Claims 99-103 depend directly or indirectly on claim 98. Claims 99 and 103 are similar to claims 93 and 94, respectively. Claim 100 recites that the amount of macromonomer ranges from about 1% to about 6% by weight, based upon the total weight of monomers, in the copolymer. This limitation is also found in pending claim 9. Claim 101 requires the presence of a delivery enhancing adjuvant, while claim 102 requires the delivery enhancing adjuvant to be selected from the group consisting of methyl laurate, isopropyl myristate, and mixtures thereof.

Support for the new claims can be found, e.g., in paragraphs [0031], [0032], [0033], [0036], [0037], [0038], and [0039], and the claims of the published U.S. application (US 2002/0119187 A1).

As a result of the amendments, claims 1-9, 16-18, 28-29, 35-36, 39-47, 52-54, and 92-103 are pending. The amended claims clearly distinguish Miranda because they exclude the presence of the polysiloxane polymer that is a key component in each of Miranda's drug delivery compositions. Garbe does not cure the deficiencies of Miranda. The amended claims, therefore, overcome the outstanding rejections over Miranda, alone or in combination with Garbe. Consequently, with the exception of new claims 95-97, applicants respectfully decline to amend

Applicant : Adam S. Cantor et al.
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the claims further to limit the composition of the acrylate/methacrylate copolymer by replacing "comprising" with "of."

All pending claims are believed to be in condition for allowance, and such action is requested. Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date:/December 2, 2009/_____

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